

Notice of Allowability

Application No.

09/760,379

Examiner

Chih-Min Kam

Applicant(s)

RAUTH ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/14/04.
2. ☒ The allowed claim(s) is/are 1,5-9,11,14 and 15.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>0704</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick Skacel on July 28 and 30, 2004.

Examiner's Amendments to the Specification:

Please insert the following paragraph at page 1, line 5:

This application claims the benefit of U. S. Provisional Application No. 60/175,958, filed January 13, 2000.

Examiner's Amendments to the Claims:

Claims 1, 9 and 11 have been amended as follows:

1 (Currently amended). A process for isolating a proteinaceous material in an aqueous sample comprising the steps:

- (a) providing an aqueous sample comprising a proteinaceous material,
- (b) contacting the aqueous sample with a solid phase having a surface on which is a mixture of hydrophobic groups and hydrophilic groups for binding the proteinaceous material to the solid phase, wherein the solid phase comprises magnetic solid particles having a diameter from ≥ 1 nm to ≤ 10 mm, and wherein the proteinaceous material is bound reversibly and [unspecifically] nonspecifically to said hydrophobic groups[;],
- (c) removing unbound components from the solid phase,
- (d) [eluting] releasing the bound proteinaceous material from the solid phase, and
- (e) removing the magnetic solid particles by magnetic separation, thereby isolating the proteinaceous material.

9 (Currently amended). A process for isolating a proteinaceous material in an aqueous sample comprising the steps:

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- (a) providing an aqueous sample comprising a proteinaceous material,
- (b) contacting the aqueous sample with a solid phase having a surface on which is a mixture of hydrophobic groups and hydrophilic groups for binding the proteinaceous material to the solid phase, wherein the solid phase comprises magnetic solid particles having a diameter from ≥ 1 nm to ≤ 10 nm, and wherein the proteinaceous material is bound reversibly and [unspecifically] nonspecifically to said hydrophobic groups[;],
- (c) removing unbound components from the solid phase,
- (d) [eluting] releasing the bound proteinaceous material from the solid phase, and
- (e) removing the magnetic solid particles by magnetic separation, thereby isolating the proteinaceous material, and wherein the molar ratio of hydrophobic to hydrophilic groups is from 10:1 to 1:10.

11 (Currently amended). The process according to claim 1, wherein removing unbound components from the solid phase having proteinaceous material bound thereto comprises [is subjected to] at least one washing [steps] step.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be the closest art to the claimed invention. Guo *et al.* (Disi Junyi Daxue Xuebao 20 (1), 85-88, 1999) teach a method for purifying recombinant human interferon- α (rhIFN- α) using magnetic affinity microsphere; Margel *et al.* (Analytical Biochemistry 128, 342-350 (1983)) teach a method for purifying antibodies using magnetic agarose-polyaldehyde microsphere beads conjugated with proteins; Anselmann *et al.* (WO 98/12727) teach the preparation of monodisperse magnetic particles with a particle size of 50-1500 nm that have a silica core coated with magnetic particles, and a silica outer layer that is modified with a silanizing agent for isolation of nucleic acids, biotin or biotinylated proteins. However, the prior art of record does not teach or suggest a method for isolating a proteinaceous material using a solid phase having a surface containing a mixture of hydrophobic groups and hydrophilic groups, wherein the solid phase comprises magnetic solid particles having a diameter from ≥ 1 nm to ≤ 10 nm, and wherein the proteinaceous material is bound reversibly and nonspecifically to the hydrophobic groups. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

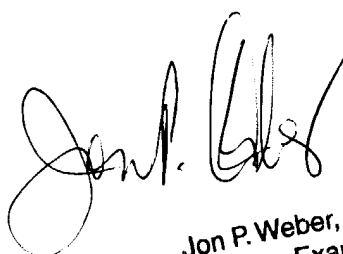
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

CMK
July 30, 2004


Jon P. Weber, Ph.D.
Primary Examiner
